

**K211478 Sterile Latex Surgical Gloves Powder Free**Sep 16, 2021  
127 days to decisionK211478 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k211478/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	May 12, 2021
Decision date	Sep 16, 2021
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aspen Glove Sdn. Bhd.</b>
Location	Georgetown, MY
Contact	Iskandar Basha bin Abdul Kadir
510(k) history	4 submissions · 4 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Liberty Management Group , Ltd.</b>
Contact	Manoj Zacharias

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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